CLAIMS

What is claimed is:

1. An oral dosage form comprising:a therapeutically effective amount of an opioid analgesic; and a dye at least partially interdispersed with the opioid; wherein the oral dosage form releases the dye upon tampering of the dosage form.

2. The oral dosage form of claim 1, wherein the tampered oral dosage form imparts a visual indication to a subject upon administration of the tampered dosage form to the subject.

3. The oral dosage form of claim 2, wherein the subject is a human subject abusing the dosage form.

4. The oral dosage form of claim 1, wherein the dye is selected from the group consisting of an FD&C dye, an FD&C lake, caramel, ferric oxide, a natural coloring agent, and a combination thereof.

5. The oral dosage form of claim 1, wherein the dye is an FD&C dye selected from the group consisting of FD&C Red No. 3, FD&C Red No. 20, FD&C Yellow No. 6, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 1, FD&C Green No. 3, FD&C Green No. 5, FD&C Red No. 30, D&C Orange No. 5, D&C Red No. 8, D&C Red No. 33, and mixtures thereof.

6. The oral dosage form of claim 1, wherein the dye is a natural coloring agent selected from the group consisting of grape skin extract, beet red powder, betacarotene, annato, carmine, turmeric, paprika, and mixtures thereof.

7. The oral dosage form of claim 1, wherein the dye is FD&C Blue No. 2.

8. The oral dosage form of claim 1, wherein the dye is in an amount of about 0.01% to about 99 % by weight of the dosage form.

9. The oral dosage form of claim 1, wherein the dye is in an amount of about 0.1% to about 50% by weight of the dosage form.

10. The oral dosage form of claim 1, wherein the dye is in an amount of about 0.1% to about 10 % by weight of the dosage form.

11. The oral dosage form of claim 1, wherein said opioid analgesic is morphine or a pharmaceutically acceptable salt thereof.

12. The oral dosage form of claim 1, wherein said opioid analgesic is hydromorphone or a pharmaceutically acceptable salt thereof.

13. The oral dosage form of claim 1, wherein said opioid analgesic is hydrocodone or a pharmaceutically acceptable salt thereof.

14. The oral dosage form of claim 1, wherein said opioid analgesic is oxycodone or a pharmaceutically acceptable salt thereof.

15. The oral dosage form of claim 1, wherein said opioid analgesic is codeine or a pharmaceutically acceptable salt thereof.

16. The oral dosage form of claim 1, wherein said opioid analgesic is tramadol or a pharmaceutically acceptable salt thereof.

17. The oral dosage form of claim 2, wherein said administration is parenteral administration.

18. The oral dosage form of claim 2, wherein said administration is nasal administration.

19. The oral dosage form of claim 2, wherein said administration is oral administration.

20. The oral dosage form of claim 1, further comprising a pharmaceutically acceptable excipient.

21. The oral dosage form of claim 20, wherein said excipient is a sustained release excipient.

22. The oral dosage form of claim 21, wherein said dosage form provides an analgesic effect for at least about 12 hours after oral administration to a human patient.

23. A method of treating pain comprising administering to a patient an oral dosage form of claims 1-22.

24. A method of preparing a pharmaceutical oral dosage form comprising combining a therapeutically effective amount of an opioid analgesic in an oral dosage form with an effective amount of a dye wherein the dye is at least partially interdispersed with the opioid analgesic and the oral dosage form releases the dye upon tampering of the dosage form.

25. The method of claim 24, wherein the tampered oral dosage form imparts a visual indication to a subject upon administration of the tampered dosage form to the subject.

26. A method of claim 25, wherein the subject is a human subject abusing the dosage form.